REMARKS

Claims 1-14, 16, 24-27, 36-56 are pending in this application. Claims 17-21 and 24-35 were previously withdrawn by the Examiner. Claims 17-21 are presently canceled without prejudice. Applicants expressly reserve the right to pursue the subject matter of these claims in both divisional and continuation applications. Claims 1-14, 16, 24-25, 36, and 38 are amended. Support for these amendments is found throughout the specification. Specifically, claims 1 and 7-8 were amended to indicate the genetic relatedness between erythrovirus variant V9 and erythrovirus B12. Support for this amendment is located on page 3, lines 31-38 and page 6, lines 11-15. Furthermore, claims 1, 7 and 36 were amended to include hybridization parameters. Support for this amendment is located on page 4, lines 6-12 and on page 9, lines 9-16. New claims 39-56 are added. Written support for the new claims can be found throughout the specification and in the original claims. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims. Applicants respectfully submit that no prohibited new matter has been introduced by the amendments.

Summary of Office Action

1. The abstract of the disclosure is objected to as failing to comply with 37 C.F.R. 1.71(b) because it did not commence on a separate piece of paper.
2. Claim 36 is objected to for allegedly failing to comply with the restriction requirement.
3. Claims 1, 7 and 36 are rejected under 35 U.S.C. 112 (second paragraph) because the term "stringent" is a relative term and fails to provide any meaningful guidance to the actual parameters encompassed by the claim language.
4. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112 (second paragraph) because the phrase "V9 variants that cannot be recognized molecularly as B19" is confusing. Since both B19 and V9 are genetically related as erythroviruses they share common structural genes and nucleotide sequences.

5. Claim 1 is rejected under 35 U.S.C. 112 (second paragraph) because the term "genomic sequences" does not make it clear whether it refers to full-length erythroviral genomic sequences or sub-genomic fragments of the full-length viral genome.
6. Claims 3-7, 10, 11, 13, 14 and 36 are rejected under 35 U.S.C. 112 (second paragraph) because it is not readily apparent if the claim language is open or closed. The claims recite SEQ ID NOS but does not indicate whether the claims encompass larger fragments "comprising" these sequences or whether the claims are directed specifically "consisting" at these sequences.
7. Claim 10 is rejected under 35 U.S.C. 112 (second paragraph) because it references a reagent for the "differential detection of type V9 erythroviruses" without making clear if the reagent is specific for just V9 isolates or if it can detect other erythrovirus isolates.
8. Claims 11 and 14 are rejected under 35 U.S.C. 112 (second paragraph) because both claims reference the "differential diagnosis" of an erythrovirus. However, both claims only detect V9 or related erythroviruses without determining which one of two or more diseases a patient is suffering from by comparing and contrasting their clinical findings.
9. Claim 11 is rejected under 35 U.S.C. 112 (second paragraph) because it omits essential positive method steps. The claim "differentially diagnoses" erythroviruses but fail to set forth the necessary steps required to perform a comparative analysis.
10. Claim 16 is rejected under 35 U.S.C. 112 (second paragraph) because it omits positive method steps required for a viral typing reaction.
11. Claim 24 is rejected under 35 U.S.C. 112 (second paragraph) because it is unclear what is meant by "screening diagnosis of infection" and it omits essential positive method steps.
12. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 112 (first paragraph) because the claims are drawn to a genus of variant erythroviruses which were allegedly not

described in the specification in such a way to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Objection to the Abstract

The abstract of the disclosure was objected to as failing to comply with 37 C.F.R. 1.71(b) because it did not commence on a separate piece of paper. A new abstract has been submitted with this paper which commences on its own paper thus abiding by the requirements set forth in 37 C.F.R. 1.71(b). Therefore, Applicants respectfully request that this objection be removed.

Objection for Failing to Reflect the Restriction Requirement

The Examiner has objected to claim 36 because it allegedly fails to reflect the restriction requirement. Applicants previously requested that the Examiner rejoin Groups I, II, and VII pursuant to the unity of invention practice under 37 C.F.R. 1.141, 1.475, and 1.499. The Examiner agreed that pursuant to unity of invention practice and that the claims in Group VII could be rejoined. This Group includes claim 36 drawn to a diagnostic kit comprising sundry nucleic acid, probes, primers and complementary sequences thereof. However, Groups VIII and IX also include claim 36. Notably, these groups include diagnostic kits that include proteins, polypeptide fragments, and antibodies. At the time of the request, claim 36 had been amended such that references to proteins, polypeptide fragments and antibodies were removed. Claim 36 as previously amended is directed toward a diagnostic kit comprising nucleic acids. The Examiner has mistakenly relied upon the previous un-amended claim 36 which incorporated a kit including polypeptides and antibodies in making his objection. Applicants respectfully request that the Examiner remove the objection to claim 36 since the claim conforms to the restriction requirement and is drawn to nucleic acids, probes, primers, and complementary sequences thereof.

Rejections Under 35 U.S.C. 112 (Second Paragraph)

Claims 1, 7 and 36 stand rejected under 35 U.S.C. 112 (second paragraph) because the term "stringent" is allegedly a relative term and fails to provide any meaningful guidance to the actual parameters encompassed by the claim language. Without acquiescing to the merits of the Examiner's arguments, the Applicants have amended claims 1, 7 and 36 to further define stringent in claims 1, 7, and 36 as "consisting of hybridization for 3 to 24 hours in a 1XSSC buffer containing 50% formamide at 42^0C and three washes of 15 minutes in a 2XSSC buffer at 60^0C." Support for this amendment is located on page 4, lines 6-12. Therefore, the term "stringent" is no longer vague and indefinite as used in claims 1, 7 and 36 and the rejection under 35 USC 112, second paragraph should be removed.

Claims 1, 7 and 8 are rejected under 35 U.S.C. 112 (second paragraph) because the phrase "V9 variants that cannot be recognized molecularly as B19" is allegedly confusing. Since both B19 and V9 are genetically related as erythroviruses they share common structural genes and nucleotide sequences. The Examiner asserts that both V9 and B12 are genetically related because they are both erythroviruses and accordingly share some common genes/ structural elements. Thus, the recitation that V9 variants cannot be "molecularly" identified as B12 is confusing. Without acquiescing to the merits of the Examiner's arguments, Applicants have amended claims 1, 7 and 8 to include "an erythrovirus V9 variant, wherein said variant displays less than or equal to 6% genetic relatedness as compared to the prototypical V9 isolate consisting of SEQ ID NO:1 and greater than or equal to 10% genetic relatedness as compared to the prototypical B19 isolate." The added claim language removes any confusion as to the relatedness of V9 and B12. Therefore, Applicants respectfully request that the rejection under 35 USC 112 be removed.

Claim 1 is rejected under 35 U.S.C. 112 (second paragraph) because the term "genomic sequences" allegedly does not make it clear whether it refers to full-length erythroviral genomic sequences or sub-genomic fragments of the full-length viral genome. Without acquiescing to the merits of the Examiner's arguments, Applicants have amended claim 1 to refer to full-length

genomic sequences, thereby eliminating any confusion. Therefore, Applicants respectfully request that the rejection under 35 USC 112, second paragraph be removed.

Claims 3-7, 10, 11, 13, 14 and 36 are rejected under 35 U.S.C. 112 (second paragraph) because it is not readily apparent if the claim language is open or closed. The claims allegedly recite SEQ ID NOS but do not indicate whether the claims encompass larger fragments "comprising" these sequences or whether the claims are directed specifically to molecules "consisting" of these sequences. Claims 3-7, 10-11, 13-14 and 36 have been amended such that any apparent ambiguity as to whether the SEQ ID NOS are directed specifically to these sequences has been removed by adding the term "comprising" before the recitation of SEQ ID NOS. Therefore, Applicants respectfully request that the Examiner remove the rejection under 35 USC 112, second paragraph.

Claim 10 is rejected under 35 U.S.C. 112 (second paragraph) because it allegedly references a reagent for the "differential detection of type V9 erythroviruses" without making clear if the reagent is specific for just V9 isolates or if it can detect other erythrovirus isolates. Without acquiescing to the merits of the Examiner's arguments, Applicants have amended claim 10 and making it clear that the reagent "specifically" detects type VP erythroviruses. Therefore, the rejection under 35 USC 112, second paragraph should be removed.

Claims 11 and 14 are rejected under 35 U.S.C. 112 (second paragraph) because both claims reference the "differential diagnosis" of an erythrovirus. However, both claims allegedly only detect V9 or related erythroviruses without determining which one of two or more diseases a patient is suffering from by comparing and contrasting their clinical findings. Without acquiescing to the merits of the Examiner's arguments, claims 11 and 14 have been amended such that the recited methods now include steps in which the products from hybridization of a sample from a subject with a erythrovirus variant V9 probe and a erythrovirus probe are compared, thereby establishing a differential diagnosis of erythroviral infection. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Claim 11 is rejected under 35 U.S.C. 112 (second paragraph) because it allegedly omits essential positive method steps. The claim purportedly "differentially diagnoses" erythroviruses

but fails to set forth the necessary steps required to perform a comparative analysis since it only provides for the detection of erythroviral variant V9. Without acquiescing to the merits of the Examiner's arguments, Applicants have amended claim 11 to include a step in which the biological sample is additionally tested for the presence of erythrovirus B12. Furthermore, a step has been added which provides for the differential diagnosis of erythroviral infection based upon the detection of hybridization products from the use of a V9 or B12 specific primer or probe. The detection of products using an erythroviral variant V9 primer or probe is indicative of an erythroviral variant V9 infection while the detection of products using a B12 specific primer or probe is indicative of a B12 erythroviral infection. Therefore, the rejection under 35 USC 112, second paragraph should be removed because claim 11 recites positive method steps necessary for the differential diagnosis of erythrovirus and is no longer vague and indefinite.

Claim 16 is rejected under 35 U.S.C. 112 (second paragraph) because it allegedly omits positive method steps required for a viral typing reaction. Claim 16 is directed toward a method of screening and typing erythrovirus V9 or a related virus by contacting the viral nucleic acid with a V9 probe. The Examiner alleges that the claim simply types erythrovirus by contacting a sample with a V9 probe. Without acquiescing to the merits of the Examiner's arguments, this claim has been amended to add a step in which the presence of the nucleic acid-probe hybrid is detected, wherein the presence of the nucleic acid-probe hybrid indicates the virus is a V9 erythrovirus. Therefore, Applicant respectfully ask the Examiner to remove the rejection under 35 U.S.C. 112, (second paragraph) since claim 16 provides the steps necessary for a typing reaction.

Claim 24 is rejected under 35 U.S.C. 112 (second paragraph) because it is allegedly unclear what is meant by "a method of *in vitro* screening diagnosis of infection in an individual" and the claim allegedly omits essential positive method steps since it fails to recite a sample preparative step, hybridization reaction and conditions, and suitable detection step. Without acquiescing to the merits of the Examiner's arguments, Applicants have amended this claim such that it is directed to "a method for the detection of an erythrovirus in an individual..." Moreover, the claim has been amended to include a step in which the individual's biological sample is

contacted with at least one nucleic acid primer or nucleic acid probe which specifically hybridizes with erythrovirus V9 and a further step in which the hybridization of the primer or probe to the nucleic acid in the sample is detected. Therefore, Applicant respectfully ask the Examiner to remove the rejection under 35 U.S.C. 112, (second paragraph) since claim 24 provides clear method steps to detect erythrovirus in an individual.

Rejections Under 35 U.S.C. (First Paragraph)

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 112 (first paragraph) because the claims are drawn to a genus of variant erythroviruses which were not described in the specification in such a way to reasonably convey to one allegedly skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner contends that variant erythroviruses are a broadly claimed genus which is not supported by the specification. Without acquiescing to the merits of the Examiner's arguments, Applicants have amended the above-mentioned claims and have limited them to specific variant erythroviruses. Specifically, the claims are now drawn to "an erythrovirus V9 variant, wherein said variant displays less than or equal to 6% genetic relatedness as compared to the prototypical V9 isolate consisting of SEQ ID NO:1 and greater than or equal to 10% genetic relatedness as compared to the prototypical B19 isolate." One of ordinary skill in the art, given the information about the sequence of B19, would readily understand that through the information provided in the specification, which could be supplemented by an alignment of known B19 nucleic acid sequences, where the V9 nucleic acid sequences disclosed in the specification could tolerate additions, deletions, or substitutions and still retain the characteristics of a V9 variant. Therefore, the 35 USC 112, first paragraph rejection should be removed because the claims are drawn to a narrowly defined sub-genus of erythrovirus variants.

Conclusion

Applicants respectfully request that the above remarks be made of record in the file history of the present application. It is respectfully submitted that all claims are now in

condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

No fee is believed owing with this response. However, should the Commissioner determine otherwise, he is authorized to charge any underpayment or credit any overpayment to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310 for the appropriate amount.

EXCEPT for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and 1.17 which may be required, including any required extension of times fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,
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